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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,322	06/14/2001	Frank Robert Busch	PC10734A US	7157

7590 04/02/2004

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/881,322	BUSCH ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-17 and 30* is/are pending in the application.

4a) Of the above claim(s) *8,9 and 11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-7, 10, 14-17, and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 22, 2003 has been entered.

The cancellation of claims 1-5 in amendments filed December 22, 2003 is acknowledged.

Claims 6-17 and 30 are pending.

Claims 8, 9, and 11-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

The outstanding rejections of claims 1-5 under 35 USC 112, first paragraph is withdrawn in view of the amendments filed December 22, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6-7, 10, 14-17, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carpino'369 (WO97/24369 from the IDS filed July 10, 2002) and Carpino'306 (US Patent 6,107,306) in view of Hahn (Chapter 284: "Systemic Lupus Erythematosus" in Harrison's Principles of Internal Medicine, 13th ed., 1994, page 1643-1648), references of record in the previous office action mailed October 16, 2003.

Carpino'369 teaches the elected compound, compound of claim 10, as the preferred growth hormone secretagogues (See the abstract and claim 90). Carpino'369 also teaches the compound can be orally administered (See page 31, line 10). Carpino'369 also teaches the compound is known to be useful to improve muscle strength and mobility as well as renal homeostasis (See page 31, line 3-4). Carpino'369 teaches the elected compound can be used with other GHS, such as GHR-6, and hexarelin, together in treating the disorders (See particularly the abstract).

Carpino'306 also teaches the same genus of compounds as Carpino'369 and those compounds are useful in treating, in addition to the above mentioned conditions, osteoporosis, improving bone remodeling, promoting cartilage formation, and treating peripheral neuropathy (See col. 27, line 16 – 21).

The references do not expressly teach the elected compound be useful in treating systemic lupus erythematosus (SLE). The references do not teach the employment of a secondary agent such as glucocorticoid, antimalarial agent, with the elected compound in the treatment of SLE.

Hahn teaches the clinical manifestation of SLE can be varied such as arthralgias, necrosis of bone, bone deformities, and peripheral neuropathy (See page 1645, Table 284-2). Hahn also teaches the antimalarial agent, quinacrine, and glucocordicoids such as prednisone, methylprednisolone, and prednisolone are useful in treating SLE (See page 1647, col. 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the elected compound to treat SLE. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a secondary agent such as glucocorticoid, antimalarial agent, with the elected compound in the treatment of SLE.

One of ordinary skill in the art would have been motivated to employ the elected compound to treat SLE because the elected compound is useful to treat the clinical manifestation of SLE such as peripheral neuropathy and renal involvement. One of ordinary skill in the art would have been motivated to employ a secondary agent such as glucocorticoid, antimalarial agent, with the elected compound in the treatment of SLE because antimalarial agent such as quinacrine and glucocorticoids such as prednisone methylprednisolone, and prednisolone are known to be useful to treat SLE. Combining and employing two or more agents which are known to be useful to treat SLE

individually into a single composition and method useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069.

Response to Arguments

Applicant's rebuttal arguments filed December 22, 2003 averring not every SLE patients having all the manifestations of SLE have been fully considered but they are not persuasive. The claims recite a method of treating SLE in any patients with SLE, which encompass the patients having SLE symptoms such as peripheral neuropathy and renal involvement. In other words, the patient populations recited in the claims include those who have SLE symptoms such as peripheral neuropathy and renal involvement. Therefore, the herein elected compound would be reasonably expected to be useful in treating SLE patients with peripheral neuropathy and renal involvement, absent evidence to the contrary. Furthermore, since the herein elected compound would be useful in treating SLE patients, concomitantly employing other known SLE treatment such as antimalarial agents, including quinacrine and glucocorticoids, with the herein elected compound for the very same treatment of SLE would be obvious (See *In re Kerkhoven* 205 USPQ 1069).

Applicant's remarks with regard to page 8 of the previous office action mailed October 16, 2003 have been considered, but are not found persuasive. The examiner did not state that the use of NSAIDs or antibiotics would be suggestive of the using growth hormone secretagogues to relieve the symptoms of SLE. The citing of Merck Manual teachings about NSAIDs and antibiotics merely points out that relieving the symptoms of SLE is often considered as treating SLE. In the same way, employing the

herein elected compound to relieve the symptoms of SLE would be considered as treating SLE.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Patent examiner
Art Unit 1617